Research Paper | Computer Science | E-ISSN No : 2454-9916 | Volume : 3 | Issue : 5 | May 2017

BLOOD GLUCOSE ESTIMATION TECHNIQUES AND DEVICES IN DISRUPTIVE TECHNOLOGY-A SURVEY

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ABSTRACT

The aging population, bar of chronic diseases, and outbreaks of infectious diseases are some of the major challenges of our human society. Health monitoring (HM) is the practical application of safety monitors to a sophisticated system so as to make sure either prediction of a potential mishap before it occurs, or detection of a mishap as it occurs. The first chronic disease for which continuous monitoring became commercially available for patients was diabetes. The prevalence of diabetes is rising all over the world due to population growth, aging, urbanization and an increase of obesity and physical inactivity. The International Diabetes Federation (IDF) estimates the total number of people in India with diabetes to be around to 87.0 million by 2030. In this paper make a brief study about glucose measurement methods, both invasive and noninvasive and its challenges as a futuristic research oriented approach in the disruptive technology or e- health monitoring.

KEYWORDS: Diabetes, Health Monitoring, Invasive, Noninvasive,Disruptive Technology.

I. INTRODUCTION

Diabetes Mellitus is a systemic disorder that results in elevated blood glucose levels due to poor insulin generation in the body and subsequently leads to many other complications [1]. Diabetes is increasing worldwide at an unprecedented pace and has become a significant health concern throughout the last 20 years. It is a major cause of mortality in the age group of 25–79 years. More than 200 million people suffer from diabetes worldwide. This figure may be double by the year 2030 [1]. Both type 1 and type 2 diabetes mellitus (T1DM andT2DM, respectively) require long-term treatment, the goal of which is to achieve optimal glucose monitoring and control with the long-term motive of reducing the risk of vascular complications while minimizing daily glycemic variations [2]. Type I DB refers to the juvenile offset stage when the pancreas cannot produce enough insulin, while type II diabetes mellitus reflects the inability of the body to use the secreted insulin. There have been continuously rapid research efforts in the field of glucose monitoring during the past few years. The frequent monitoring of blood glucose is critical for diabetic management, as the maintenance of physiological glucose level, i.e., 4–8 mM (72–144 mg/dL), is the only way that a diabetic can lead a healthy lifestyle by avoiding life-threatening diabetic complications, such as diabetic retinopathy, kidney damage, heart diseases, stroke, neuropathy and birth defects [3]. Self- monitoring of blood glucose levels provides diabetes patients with a continuous, robust and reliable method to determine the blood glucose concentration, as opposed to conventional lab tests. Frequent verification of glucose levels is crucial in the treatment of diabetes, and it aids patients in preventing and detecting hyper or hypoglycemia events. Some of commercial glucose monitors exist, most of them requiring a small drop of blood obtained on the tip of the fingers (commonly referred to as finger-stick testing). These are invasive methods, and are highly discomfort for patients due to the frequent puncturing several times per day. Additionally, measurements with these devices usually present an error of approximately 6-7%. This percentage may increase depending on the size and quality of the sample, human error during sample extraction, faulty calibration, humidity, and lack of hygiene in the extraction area. In this paper we are providing how these methods (invasive and noninvasive) are very important for futuristic research in the field of noninvasive continuous glucose monitoring for effective health monitoring for diabetes patients in disruptive technology.

II. AFFORDABILITY AND ACCESSIBILITY

A. Helath monitoring industry.

The problems facing the health care industry actually aren't similar. The products and services offered in nearly every industry, at their outset, are so complicated and expensive that only people with a lot of money can afford them. It's very expensive to receive care from highly trained professionals. At some point however these industries were transformed making their products and services so much more affordable and accessible that a much larger population of people could utilize them, and people with less training could competently provide them and use them. We termed this agent of transformation as disruptive innovation. It consists of three elements, Technological enabler, Business model innovation, value network for e health.

Technological enabler: Problems that previously required unstructured processes of intuitive experimentation to resolve.

Business model innovation: Can profitably deliver these solutions to customers affordable and easily accessible.

Value Network: A commercial infrastructure whose constituent companies have consistently disruptive, mutually reinforcing economic models.

III. ROLE OF INFORMATION TECHNOLOGY IN THE DISRUPTION OF HEALTH CARE

Information technology will play two crucial roles in facilitating the emergence of disruptive business models. First IT will be the enabling mechanism that shifts the locus of care when this is desirable and feasible from solution shops to facilitated networks. It will enable doctors, nurses, and patients to help each other, and it will provide the enabling fuel for primary care doctors to disrupt specialists and for nurse practitioners to disruptive doctors. Second the transition from medical records based on pen and paper to ones that are portable, easily accessible, and interoperable will not just sustainably reduce the costly paperwork that burdens today's caregiver.

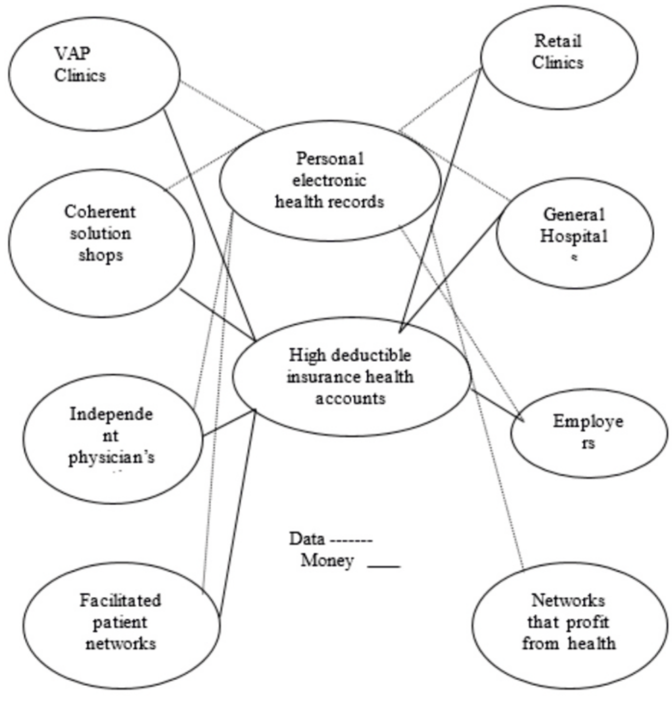

Figure1: Disruptive value networks

It will be the primary mechanism of coordination among the providers in the disruptive value network, as depicted in figure 1.These will make it easier to avoid costly mistakes and will enhance the involvement of patients in their own care.

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IV. EVOLUTION OF PATIENT HEALTH RECORDS

The role of IT in transforming the cost and quality of health care is through the enhancement of medical records. In its most basic form, an electronic medical record (EMR) is simply the electronically stored version of what has always been recorded with pen and paper. EMR is very important document for every patient and some countries are pervasively kept in a standard format so any physician can instantly access the medical records of any patient at the emergency time. New EHR (electronic health record) tools have recently launched by Microsoft and Google and innovators like docvia have enabled patients anywhere in the world to manage their health using the internet or their mobile phones for less than 10 cents per encounter. These types of records are very useful in the disruptive technology. To highlight the importance of using EHR for health monitoring we give an overview of the different forms of blood glucose monitoring devices available [4]. We distinguish between alarm systems and long-term monitoring systems for diabetes patient. The survey of different glucose monitoring devices, methods, results and its pros and cons are summarized for futuristic research in the disruptive technology.

V. BLOOD GULCOSE MONITORING DEVICES COMPARISION

Currently, monitoring blood glucose concentration is most frequently measured through invasive techniques. The most common of the techniques is a blood glucose meter [10]. The measurement utilizes a lancing device on the side of a finger to produce a drop of blood. The drop of blood is placed on a test strip and the blood glucose meter calculates the blood glucose concentration and displays the results to the user. Unfortunately, this method can be painful and painstaking to the user as the process needs to be repeated several times a day to ensure proper glucose concentration levels. The blood glucose meter has an error of up to ±10% [5]. Opposed to invasive devices, non-invasive blood glucose monitors offer a solution to measure proper blood glucose levels without puncturing the skin.

Non-invasive blood glucose monitoring has been tried with variety of different techniques. Here we put a comparative analysis for both methods for research oriented approach.

Invasive Methods:

1. Urinary glucose measurement:

Device: Jules Maumene was first to develop a very simple reagent 'strip' in 1850, in which drops of urine were added to strips of sheep's wool containing stannous chloride, which gave a black product if sugar was present.

Year: 1850.

Pros&cons: It was also possible to detect excess sugar in the urine and various chemical tests were developed, although there was still no treatment for diabetes, except with diet. Improvements in reducing sample volume, improving color stability and precision, manual blood sugar estimations in the laboratory were limited and mainly confined to diagnosis and critical care management, rather than for monitoring purposes.

2. Device name: Dexcom SEVEN® Plus
Type: Invasive

Method: glucose sensor; sensor lifespan: 168 h; length of sensor probe: 13 mm; gauge of sensor probe: 26 mm; sensor warm up: 2 h; calibration every 12 h, but twice within the first 30 min.

Pros: use FDA-approved glucose sensor that can be used for up to seven days; precisely detect hypoglycemic glucose level; water-resistant transmitter with built-in battery; transmits glucose sensing data to the handheld receiver within five feet range every 300 seconds; receiver shows trends and current glucose level; stores up to 30 days of glucose trends along with a record of activities and events; comes with Dexcom® Data Manager 3 software, which provides better insight into the ways to improve glycemic control.

Cons: invasive; is a previous generation of CGMS that is not being used anywhere; calibration is difficult; Sensor have to change frequently. Reliability: MARD in euglycemia region = 18.2%; MARD in hypoglycemia region = 21.5%; Clarke EGA in euglycemia region = 97.3% in A + B, 91.3% in A; Clarke EGA in hypoglycemia region = NA. MARD in hypoglycemia region = 21.5% ; aggregate MARD = 16% ; 76% of DG4P sensors had an individual MARD of ≤20%; DG4P had a mean absolute difference of 16 mg/dL for hypoglycemia (Yellow Springs Instrument Company's YSI blood glucose analyzer < 70 mg/dL) .

Cost: Rs: 81,632 for CGMS

Figure2: Dexcom SEVEN® Plus

3. Device name: Dexcom G4TM PLATINUM

Type: Invasive

Method: glucose sensor; sensor lifespan: 168 h; length of sensor probe: 13 mm; gauge of sensor probe: 26 mm; sensor warm up: 2 h; calibration every 12 h, but twice within the first 30 min.

Pros: compact, wearable and light-weight; measures glucose continuously every 5 min; transmit glucose readings to the receiver up to a distance of 6 m; receiver with colored screen and alarm alerts for high and low glucose levels and when the glucose levels are rising or falling quickly.

Cons: invasive; requires calibration with blood glucose testing every 12 h; requires a change of the sensor after a few days.

Cost: Rs: 81,632 for CGMS

Figure 3: Dexcom G4TM PLATINUM

4. Device name: Guardian Real-Time
Type: Invasive

Method: glucose sensor; sensor lifespan: 72 h; length of sensor probe: 14 mm probe gauge of sensor probe: 23 mm; sensor warm up: 2 h; calibration at 2 h, 8 h and then every 12 h.

Pros: measures glucose levels in the interstitial fluid every 10 s; wireless transmitter attached to a glucose sensor transmits average glucose reading to the monitor every 5 min; predictive alerts notify the user up to 30 min before they are predicted to reach a personal low or high glucose level.

Cons: invasive invasive; requires calibration with blood glucose testing; requires a change.

Cost: Rs: 95,221 for CGMS

Figure 4: Guardian Real-Time

5. Device name: HG1-c
Type: Invasive

Method: Raman spectroscopy

Pros: compact, wearable and light-weight; non-invasive glucose monitoring; CE-approved; small and water-resistant glucose sensor; glucose measurement every 5 min; precision comparable to blood glucose meters;

Cons: calibration is difficult.

Cost: Rs: 2,71,590 for CGMS

Figure 5: HG1-c

6. Device name: GlucoTrack™
Type: Invasive

Method: ultrasound, electromagnetic and heat capacity

Pros: compact and light-weight; big LCD screen; high exactness due to the use of various non-invasive glucose monitoring techniques; alerts for hypo- and hyper-glycemia; multi-user support; easy calibration procedure with the calibration being valid for 30 days; USB and infra-red connectivity; data storage capacity; software for data analysis; readings unaffected by daily routine activities; better correlation with glucose meters and analyzers; and high accuracy in clinical trials.

Cons: must be individually calibrated against invasive basal and post-prandial blood glucose references before use; requires more improvements in the calibration procedure and algorithm for data processing.

Cost: Rs: 1,20,590 for CGMS

Figure 6: GlucoTrack™

VI. CURRENT RESEARCH ABOUT NON-INVASIVE METHODS

Non-invasive blood glucose monitoring methods have been studied and explored by many researchers around the world over the years and the most commonly approaches are by using optical detection or optical scanning methods., i.e., polarimetry, Raman spectroscopy , photo acoustic spectroscopy, Mid-Infrared (MIR) spectroscopy using an Attenuated Total Reflection (ATR) prism , and Near- Infrared (NIR) spectroscopy .

NIR spectroscopy is used for development of a non-invasive blood glucose monitoring system in this study. The advantages of NIR spectroscopy over MIR spectroscopy include better penetration depths (shorter wavelength) and small background interference due to water absorption [6]. The greater penetration depths are preferred for monitoring blood glucose in capillaries and glucose in interstitial fluid and tissue. Besides, NIR spectroscopy also offers advantages over Raman spectroscopy, such as higher SNR and broadband light source is used for of the highly monochromatic source necessary for Raman spectroscopy. Non-invasive determination of the glucose also promotes continuous testing, adequate control, complications reduction and consequently health care cost reduction.

Near infrared spectroscopy (NIR): The light focused on the body is randomly absorbed and scattered, due to its interaction with the chemical components within the tissue. Glucose concentration could be calculated by variations of light intensity both transmitted through a glucose containing tissue and reflected by the tissue itself.

Advantage: High accuracy. Measuring signal has better energy compared with MIR spectroscopy.

Raman spectroscopy is based on the use of a laser light to induce oscillation and rotation in molecules &consequent emission of scattered light influenced by this molecule vibration, which depends on the concentration of the glucose molecule.

Advantage: Fixed wavelength lasers at usually low cost can be used. The limitations are related to non-stable of the laser wavelength and intensity, and long spectral acquisition times.

Fluorescent spectroscopy: This technique analyses the fluorescence from the sample. It was also proved that fluorescence intensity was depending upon glucose concentration in the solution.

Advantage: Light in the visible spectrum can be used and more adequate for studying fluorescence of tissues.

Polarization Change: It is depending on the phenomenon that occurs when polarized light transverses a solution containing optically active solutes (such as chiral molecules). Glucose is a chiral molecule, and its light rotation properties have been known for a long time. Indeed, investigation of the polarization variation induced by glucose is reported to the first proposed non-invasive method for glucose measurement in humans.

Advantage of Polari-metric technique is that this can make use of visible light, easily available.

Mid-infrared spectroscopy is based on light in the 2500–10,000nm spectrums. The physical principle is similar to that of NIR. When compared to NIR method, however, due to the higher wavelengths and Mid-infrared exhibits decreased scattering phenomena, and increased absorption.

Advantages and challenges in non-invasive glucose monitoring for spectroscopic techniques.

	Advantages	Challenges	Performance parameters
NIR spectroscopy 6-13	• Well established analytical technique • Non-destructive analysis • Efficient removal of most interferents • Successfully tested in humans	• Requires multivariate analysis • Device exists in the macroscale only, requires miniaturization Scattering in skin	Average absolute error: 1.1 mmol/l Root mean standard error: 1.02-1.88 mmol/l Mean prediction error: 9.3%
Raman spectroscopy 6,16-20	• Spectral signature less influenced by water compared to NIR spectroscopy • Measurements directly from biofluids • Feasible transcutaneously in forearms	• Long collection times • Collection times reducible by with lasers, but not without harm • Proof of functionality in humans not presented	Concentration estimated down to: 0.7 mmol/l (in water) 7.2 mmol/l (in bioreactor material) 2.5 mmol/l (in serum and plasma samples)
Bioimpedance spectroscopy 21-23	• Low cost instrumentation • Simple application in practice • On-line monitoring available • Safe and with fast response	• Very long calibration process with current devices • Susceptible to interference by different phenomena such as movement, sweat and temperature	Correlation coefficient blood glucose in low control outpatient conditions: 0.64
Thermal emission spectroscopy 24-25	• Prototype has shown acceptable accuracy • No daily calibrations needed	• Intensity of radiation by eardrum is affected by its thickness, which is variable in humans • Results of measurements not acceptable under clinical standards	Mean error: 0.638 mmol/l

Breath Chemical Analysis
Another chemical analysis technique involves the measurement of acetone in an exhaled breath. It has been shown that the level of acetone in exhaled breaths sharply rises in diabetic patients, and increases as a function of blood glucose levels [9]. A system has been designed which can chemically analyze exhaled air, which can be used to determine blood glucose levels.

Evolution of blood glucose systems for self-monitoring
- 1957 First reagent strip using glucose oxidase reaction Clinistix Ames
- 1964 Modified reagent strip for blood glucose Dextrostix Ames
- 1970 Reflectance photometry with Dextrostix Ames Reflectance Meter Ames
- 1973 Mains-powered, single analogue scale Eyetone Ames
- 1974 Reduced blood volume, strip wiping Reflomat Boehringer Mannheim
- 1980 Digital display, whole blood standard Dextrometer Ames

- 1980 Automatic timing Glucochek/Glucoscan Lifescan
- 1981 Improved countdown timer with audio alarm Glucometer I Ames
- 1981 Stored calibration, low/high result alarms Glucometer I Ames
- 1986 Data storage of results Glucometer M Ames
- 1987 Non-wipe, automatic timing, 45-second measurement time test strip OneTouch Lifescan
- 1987 First biosensor enzyme electrode sensors Exactech Medisense
- 1991 Capillary-fill sampling with 5 μL blood HemoCue
- 1997 Downloading results to personal computers Glucometer Esprit Bayer
- 2001 Plasma calibration OneTouch Ultra Johnson & Johnson
- 2002 Catering for visually impaired persons AccuChek Voicemate Roche
- 2003 Biosensor using coulometry, alternative site testing Freestyle Freedom Abbott
- 2003 Autodisc of 10 strips replaced reagent strips Ascensia Breeze Bayer
- 2005 17-test strip barrel AccuCheck Compact Roche
- 2008 Talking blood glucose meter SensoCard Plus BBI.

VII. DISCUSSION

The key challenges for the development of next-generation CGMS for diabetic management are the reduce in the operational cost, development of prospective NGM techniques for precise and specific glucose detection, significant reduction or obviation of calculation and warm up periods, improvement of signal-to-noise ratio (SNR) and sensitivity, development of wearable CGMS, evaluation of analytical performance and reducing the time taken for glucose measurement [7]. In this survey discussed and collective very informative CGMS devices and its advantages and disadvantages. Based on this survey now days so many researches is going on noninvasive techniques and how we can deliver the diagnostic and monitoring devices affordable prices to all peoples. In the new advance technology (disruptive) also concentration on how to make E-health records at low cost for especially elderly peoples. Non-invasive blood glucose measurement is used to measure blood glucose levels without taking blood. Till now the technologies available are pricking blood from body which is painful, costly and not used for continuous monitoring. So non-invasive blood glucose measurement is used for continuous monitoring of glucose levels in blood which is very much needed in present market.

VIII. CONCLUSION

In this research survey discussed about both invasive and noninvasive techniques, most of the commercially-available CGMS are based on invasive techniques and employ a difficult procedure, where the diabetic has to be trained and educated to use it. They do not obviate the finger stick blood tests by glucose meters, as the CGMS still needs to be calibrated several times by blood glucose meters. However, there is a need to change the invasive sensor of CGMS after every few days. In addition, there is patient discomfort and skin irritation. Therefore, it is a critical need for cost-effective NGM technique-based CGMS that can alleviate the pain and suffering associated with glucose monitoring, which will motivate diabetics to use the CGMS to sustain geuglycemia. Based on the analysis how to provide a better and low cost CGMS for elderly people in a noninvasive method. A Disruptive technology can give solution for this, to make the medical records, drugs, methodology, specialist, etc, everything in E-form to caregiver, network hospitals. CGMS still requires tremendous improvements in order to address the challenges of cost-effectiveness, the use of NGM technology; rapid response, elimination of interference, higher precision, improved calibration, increased comfort and patient safety and significantly improved software and device features.

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